

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicant(s): Donoho *et al.*

Group Art Unit: 1653

Application No.: 09/691,344

Examiner: R. Mitra

Filed: 10/18/00

Title: Novel Human Proteins and Polynucleotides
Encoding the Same

Atty. Docket No.: LEX-0071-US

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AMENDMENT AND RESPONSE TO OFFICE ACTION
DATED OCTOBER 1, 2002

Commissioner for Patents
Arlington, VA 22202

Sir:

Applicants acknowledge the receipt of the Office Action ("the Action") mailed on October 1, 2002 (Paper No. 12), which has been carefully reviewed and studied. The Examiner is respectfully requested to enter the following amendments. Reexamination and reconsideration of the application is requested in view of the following amendments and remarks. In order to facilitate the Examiner's evaluation of the application, Applicants have attempted to address the objections and rejections in Paper No. 12 in the same order in which they were originally raised.

The response is due on January 1, 2003 which is a PTO holiday and is therefore extended until January 2, 2003. The response is thus timely filed. Applicants believe no fees in addition to the fee for the extension of time are due in connection with this response. However, the Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 50-0892.

Also enclosed as Exhibit A is a clean copy of the pending claims; as Exhibit B is a marked up copy of the original claims; as Exhibit C is a marked up copy of the original abstract; as Exhibit D is a clean copy of the amended abstract; as Exhibit E is a copy of the nucleic acid sequence information provided with the accession number (HS94G16/Z85999), which was identified in Reference BN of the supplemental IDS (Paper #4).

AMENDMENT

In the Specification:

Please replace the original abstract with the following abstract:

-Novel human CUB domain containing protein polynucleotide and polypeptide sequences are disclosed that can be used in therapeutic, diagnostic, and pharmacogenomic applications.--

In the claims:

Pursuant to Applicants election, in a telephone conversation, in response to restriction, please cancel claims 4 and 5 without prejudice and without disclaimer, as being drawn to non-elected inventions.

Please amend claims 1 and 2, so that the text of the amended claims reads as follows.

1. (Amended) An isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 3.

2.(Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:

- (a) encodes the amino acid sequence shown in SEQ ID NO:4; and
- (b) hybridizes under highly stringent conditions to the complement of the nucleotide sequence of SEQ ID NO: 3.

Please add new claims 6 and 7.

-6.(New) An expression vector comprising a nucleic acid sequence of Claim 2.

7.(New) A cell comprising the expression vector of Claim 6.--

RESPONSE

I. Status of the Claims

Claims 4 and 5 have been cancelled without prejudice and without disclaimer, as being drawn to non-elected inventions. Claims 1 and 2 have been amended. New claims 6 and 7 have been added. Claims 1, 2, 3, 6 and 7 are therefore presently pending in the case. For the convenience of the

Examiner, a clean copy of the pending claims is attached hereto as Exhibit A. In compliance with 37 C.F.R. § 1.121(c)(1)(ii), a marked up copy of the original claims is attached hereto as Exhibit B. A marked up copy of the original abstract is attached hereto as Exhibit C and clean copy of the amended abstract is attached hereto as Exhibit D.

II. Support for the Amended Specification and Claims

Claim 1 has been amended to further clarify the claim. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least in Claim 1 and the sequence listing as originally filed.

Claim 2 has been amended to further clarify the claim, and to recite that the stringent hybridization conditions are highly stringent hybridization conditions. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least in Claim 2 as originally filed and at page 4, lines 17-24.

New Claim 6 has been added to more clearly claim aspects of the invention. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least at page 11, lines 3-9.

New claim 7 has been added to more clearly claim aspects of the invention. Claim 7 finds support throughout the specification as originally filed, with particular support being found at least at page 11, lines 9-15.

As the amendments to claims 1 and 2 and new claims 7 and 8 are fully supported by the specification and claims as originally filed, they do not constitute new matter. Entry therefore is respectfully requested.

III. Objections

The Action alleges that the oath or declaration is defective. Therefore, a new Declaration is enclosed.

The Action objects to the abstract of the disclosure because it allegedly fails to disclose any information unique and specific to the elected invention. Applicants in no way agree and submit that

abstracts of this type have been acceptable to the U.S.P.T.O. as evidenced at least by the abstracts of issued U.S. Patents Nos: 6,403,784, 6,433,153, 6,441,153, 6,441,154, 6,444,456 and 6,448,388. However, in order to progress the application more rapidly towards allowance Applicants have amended the abstract of the present application to read:

Novel human CUB domain containing protein polynucleotide and polypeptide sequences are disclosed that can be used in therapeutic, diagnostic, and pharmacogenomic applications.

The Action also indicates that Reference BN identified on the supplemental Information Disclosure Statement (IDS:1449) filed on February 20, 2001 (Paper #4) has not been considered because it consists of only one page, “not the entire document.” Applicants invite the Examiners attention to the fact that Reference BN identifies EMBL entry HS94G16, which is also identified as accession number Z85999. The portion of the document which was not provided with Reference BN, contains the nucleic acid sequence of this entry. This portion of the reference was not included because it is Applicants belief that consideration of Reference BN is probably more easily and accurately executed through the use of an electronic sequence comparison, blast like analysis, as opposed to painstaking base by base comparison over 30+ pages of sequence. In case the Examiner should disagree, Applicants respectfully submit a copy of the nucleic acid sequence information obtained on line at NCBI using the accession numbers identified in Reference BN of Paper #4 as Exhibit E for the convenience of the Examiner.

IV. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Allegedly because Claim 1 encompasses subject matter that is not defined in the specification.

35 U.S.C. § 112, first paragraph, requires that the specification contain a written description of the invention. The Federal Circuit in *Vas-Cath Inc. v. Mahurkar* (19 USPQ2d 1111 (Fed. Cir. 1991); “*Vas-Cath*”) held that an “applicant must convey with reasonable clarity to those skilled in the

art that, as of the filing date sought, he or she was in possession *of the invention.*" *Vas-Cath*, at 1117, emphasis in original. However, it is important to note that the above finding uses the terms reasonable clarity to those skilled in the art. Further, the Federal Circuit in *In re Gosteli* (10 USPQ2d 1614 (Fed. Cir. 1989); "Gosteli") held:

Although [the applicant] does not have to describe exactly the subject matter claimed,
... the description must clearly allow persons of ordinary skill in the art to recognize
that [he or she] invented what is claimed.

Gosteli at 1618, emphasis added. Additionally, *Utter v. Hiraga* (6 USPQ2d 1709 (Fed. Cir. 1988); "Utter"), held "(a) specification may, within the meaning of 35 U.S.C. § 112 ¶1, contain a written description of a broadly claimed invention without describing all species that claim encompasses" (*Utter*, at 1714). Therefore, all Applicants must do to comply with 35 U.S.C. § 112, first paragraph, is to convey the invention with reasonable clarity to the skilled artisan.

Further, the Federal Circuit has held that an adequate description of a chemical genus "requires a precise definition, such as by structure, formula, chemical name or physical properties" sufficient to distinguish the genus from other materials. *Fiers v. Sugano*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993; "Fiers"). *Fiers* goes on to hold that the "application satisfies the written description requirement since it sets forth the . . . nucleotide sequence" (*Fiers* at 1607). In other words, provision of a structure and formula - the nucleotide sequence - renders the application in compliance with 35 U.S.C. § 112, first paragraph.

More recently, the standard for complying with the written description requirement in claims involving chemical materials has been explicitly set forth by the Federal Circuit:

In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.

Univ. of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Thus, a claim describing a genus of nucleic acids by structure, formula, chemical name or physical properties sufficient to allow one of ordinary skill in the art to distinguish the genus from other materials

meets the written description requirement of 35 U.S.C. § 112, first paragraph. As further elaborated by the Federal Circuit in *Univ. of California v. Eli Lilly and Co.*:

In claims to genetic material ... a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity of members of the genus. (Emphasis added)

Thus, as opposed to the situation set forth in *Univ. of California v. Eli Lilly and Co.* and *Fiers*, the nucleic acid sequences of the present invention are not distinguished on the basis of function, or a method of isolation, but in fact are distinguished by structural features - a chemical formula, *i.e.*, the sequence itself.

Using the nucleic acid sequences of the present invention (as set forth in the Sequence Listing), the skilled artisan would readily be able to distinguish the claimed nucleic acids from other materials on the basis of the specific structural description provided. Polynucleotides comprising the nucleotide sequence of, for example, SEQ ID NO:3 or a nucleotide sequence that encodes SEQ ID NO:4, are within the genus of the instant claims, while those that lack this structural feature lie outside the genus. Thus those of skill in the art would have known how to make and use the invention as claimed in original Claim 1. However, Applicants respectfully submit that as Claim 1 has been revised to read on the full-length sequence of SEQ ID NO: 3 this issue has been rendered moot. Indeed, the Action (page 5, lines 4-5) states "It is clear from the specification that Applicants were in possession of SEQ ID NO: 3 at the time the invention was made. Thus, Applicants submit that the present invention meets both the requirements for written description and enablement and respectfully request that the rejection of Claim 1 under 35 U.S.C. § 112, first paragraph, be withdrawn.

The Action also rejects claims 1 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants in no way agree with the Examiner's position that original Claim 1 lacks enablement. The relevant question is would the skilled artisan know how to make and/or use the claimed nucleic acid sequence? The answer is clearly yes, the skilled artisan would easily recognize 24 contiguous nucleic acids derived from any of the nucleic acid sequences described in the sequence listing and know how to make an isolated nucleic acid comprising 24 contiguous nucleic acids of SEQ ID NO: 3. Those of skill in the art would also know how to use a nucleic acid molecule that comprises 24 contiguous bases of nucleic acid sequence of SEQ ID NO: 3. In fact, Applicants note that the entire DNA gene chip industry is based on the use of 24 or more contiguous bases of nucleic acid sequence. Therefore, Applicants submit that those of skill in the art would also be able to make and use the present invention. Thus, one skilled in the art would know how to make and/or use the nucleic acid sequence of original Claim 1 and the present invention is thus enabled. Again, however, Applicants submit that this rejection has been avoided by revision of Claim 1 to read on the full-length molecule, which those of skill in the art would clearly recognize as a kinase and know how to make and use. Therefore, Applicants respectfully request that the rejection of Claim 1 under 35 U.S.C. § 112, first paragraph, be withdrawn.

V. Rejection of Claims 1-3 Under 35 U.S.C. § 112, Second Paragraph

The Action next rejects claims 1-3 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Action alleges that Claim 1 and dependent Claim 3 are indefinite for reciting the term "NHP". In response, Claim 1 has been revised.

The Action next alleges that Claim 3 is indefinite for reciting the term "cDNA" which is said to be inherent in Claim 1. Applicants respectfully submit that there are those who would define a cDNA strictly as that which is derived by reverse transcription from RNA only. Clearly, as the Examiner can readily appreciate, under such a definition, Claim 3 does further limit Claim 1.

The Action also rejects Claim 2 as allegedly indefinite based on the term "stringent" in regards to hybridization conditions. While Applicants submit that the term is sufficiently definite, as a number

of stringent hybridization conditions are defined in the specification and would be known to those of skill in the art, solely in order to progress the case more rapidly toward allowance the claim has been revised to recite "highly stringent" hybridization conditions. As the specification provides specific teaching regarding "highly stringent hybridization conditions", at least at page 4, lines 17-24. Finally, the Action rejects Claim 2 as allegedly indefinite based on hybridization to the coding strand of the sequence. Applicants submit that revised Claim 2 even more clearly meets the requirements of 35 U.S.C. § 112, second paragraph. Applicants stress that "a claim need not 'describe' the invention, such description being the role of the disclosure". *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). Based on the foregoing, Applicants submit that Claim 2 is sufficiently definite, and respectfully request withdrawal of this rejection.

VI. Rejection of Claims 1 and 3 Under 35 U.S.C. § 102(e)

The Action next rejects claims 1 and 3 under 35 U.S.C. § 102(e), as being anticipated by Strachan *et al.* (US 6,242,419, filed August 26, 1999, issued June 5, 2001). While Applicants do not necessarily agree with the present rejection, as Claim 1, and thus dependent Claim 3, have been amended to recite the complete nucleotide sequence of SEQ ID NO:3, which is neither taught nor suggested by Strachan *et al.* (US 6,242,419, filed August 26, 1999, issued June 5, 2001). Applicants therefore submit that the rejection of claims 1 and 3 under 35 U.S.C. § 102(e) have been thus avoided, and respectfully request withdrawal of the rejection.

VII. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Mitra have any questions or comments,

or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

01/02/03

Date


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